REMARKS

Please reconsider and allow this application.

Applicants respectfully present claims 17-40 and new claim 41. Claims 17, 19, 20 and 35 have been amended. The amended claims reflect editorial revision, and are not intended as limiting or narrowing the scope of the inventions. For instance, amended claim 35 relates to the composition in the form of an isotonic beverage or sports bar, consistent with the original claims and the specification at page 3, lines 17-23. New claim 41 finds basis in the powder composition disclosed at page 12, Table 2, which contains "about 7 wt.%" of leucine and also of phenylalanine (7.047 Wt. %).

Applicants respectfully request the Examiner to enter the amended and new claim. The amended claims are thought to retain the scope of the claimed subject matter while making explicit what was implicit from the claims already of record. The new claim 41 avoids new matter while defining over the references of record. Entry of the claims presented will reduce, if not eliminate, issues for a possible appeal.

Please reconsider and withdraw the formality rejections. The rejection based on the "range of 0.2 to 20 weight percent" and the reference to "each" in claim 17 would seem to have been misplaced inasmuch as the amounts recited clearly related to the amino acids, as would be seen upon reading claims 36, 37 or 28. Hence the amendment to claim 17 merely makes explicit what was clear to persons skilled in the art, which therefore does not narrow the claim scope. (The specification is also instructive at page 2.) Amended claims 18 and 19 similarly make explicit what was implicit. Amended claim 20 similarly makes explicit - what was already explicit - using different words. Claim 33 is corrected to depend from claim 17, which Applicant's acknowledge is in accord with the Examiner's helpful suggestion. Claim 35 is amended, as discussed above, to make explicit, what was already understood.[1]

The Examiner rejected claims 17, 19-21, 26-33, 35 and 39-40 as anticipated by U.S. Patent 6,051,236. The Examiner also rejected claims 17, 21-25, 33-34 and 36-38 as obvious over U.S. Patent 6,051,236. The Examiner rejected claims 17-22, 24-28, 21-34 [sic] and 36-

---

[1]The claim did not, as suggested in the Office Action "further comprises ..." The rejection should not have been made in the first instance.

39 under 35 U.S.C. § 103(a) over U.S. Patent No. 5,776,887. The Examiner interposed an obviousness rejection of claims 17-22, 24-33 and 35-39 over EP 0421309A2. The Examiner also rejected claims 17-19, 21-39 over PCT Patent Publication WO93/22909.

Applicants respectfully traverse these rejections and request their reconsideration and withdrawal.

Claim 17 and claims depending therefrom define novel and unobvious inventions.

(A) As stated in the Office Action, the Portman '236 reference "does not teach the composition where the peptide chain length is 20 - 40 or 3 - 20 amino acids." Office Action, page 6.

The "Portman ['236 reference] does not specifically teach a hydrolyzed peptide derived from wheat protein or the composition containing a lipid emulsifier." Office Action, page 6.

The obviousness rejection has been stated in the Office Action as being solely over the Portman '236 reference. I t is therefore unclear what the Examiner meant by the off hand references to the Wilbert et al. and Kingham references in the Office Action at the top of page 7. Please withdraw the rejection over the Portman '236 reference, or provide a further office action, if this case is not allowed.

The present invention is directed generally to compositions that are administered to a subject and are capable of inducing a maximal insulinotropic effect for an enhanced recovery after physical exercise.

The invention may therefore concern compositions that contain the recited carbohydrate and peptide material, and as additional components, 0.2 to 20 weight percent of leucine and 0.2 to 20 weight percent of phenylalanine showing the desired insulinotropic effect; see Table 1 on page 11 of the present specification. From said Table 1 it is evident that:

- the amino acids arginine and glutamine imperative according to Portman do not contribute to the desired enhanced plasma insulin response (see results of drinks 6-9): and
- the amino acids leucine and phenylalanine are responsible for the enhanced plasma insulin response.

In contrast, the Portman '236 reference does not evidence conception of leucine's impact on enhancing a subject's recovery after physical exercise.

Indeed, Applicant's discovery relates, in part, to the realization that both leucine and phenylalanine have impact on the enhanced plasma insulin response, *i.e.*, the enhanced recovery after physical exercise.

Since Portman '236 does not describe the inventions, nor would it have suggested them, the claims are thought to define unobvious inventions over this reference.

(B) The Wilbert et al '887 reference neither teaches nor would it have suggested a composition in accordance with present claim 17, and claims 18-22, 24-28, "21-34" [sic], and 36-39.

According to the Office Action, "Wilbert does not teach the composition comprising the specific amounts of carbohydrates, protein and amino acids or peptide chain lengths as claimed." Office Action, page 8.

Accordingly, it follows there is no disclosure in the Wilbert et al. '887 reference which would have suggested the combination of additional amino acids or the further presence of the another specified amino acid(s).

The Wilbert et al. '887 reference would furthermore have directed a person of ordinary skill in the art to include fibers. Those skilled in the art would have recognized that dietary fibers can delay gastric emptying and therefore delay the transfer of carbohydrates to the small intestine where the actual absorption of carbohydrates occurs. The dietary fibers

can furthermore delay the absorption of carbohydrates in the small intestine as the fibers directly interfere with the absorption. It is not seen where the prior art teaches to omit one of its essential ingredients.

This reference seeks to avoid glucose peaks as suggested at column1 line 59 to column 2 at line 12. This penchant for a low glycemic index would seem to have been a teaching away from the concepts pertinent to the present invention. That low glycemic index would be related, of course, to the required presence of fibers, which is another reason why the reference neither discloses nor would it have suggested the cited claimed inventions.

Accordingly, please reconsider and withdraw the rejection.

(C) Claims 17-22, 24-33 and 35 and 39 define novel and unobvious inventions over the Kahn et al. EP '309 reference (EP 0421309A2). This reference does not disclose, suggest or teach the additional presence of free leucine and phenylalanine.

As the Office Action reports, "Kahn does not teach the composition comprising the specific amounts of carbohydrates, protein and amino acids or peptide chain lengths as claimed." Office Action, page 10.

In the present claimed inventions, the additional free leucine and phenylalanine are important in obtaining the insulin response required for stimulating the glycogen resynthesis after exercise.

The present invention may address regulating carbohydrate metabolism whereas the cited Kahn et al. reference concerns regulating the protein metabolism (EP '309 at page 2, line 10). With respect to Kahn, compared to the present invention, it is brought to the fore that the present composition comprises "peptide material" which has been defined as a protein hydrolysate, containing all types of peptides as well as a certain amount of free amino acids resulting from the hydrolysis as is defined in the present specification, at page 2, lines 20-23. However, according to the invention, an <u>additional</u> amount of two specific free

amino acids, i.e., leucine and phenylalanine, may be used for achieving the surprising impact on the enhancement of the recovery after physical exercise, as aspect which is not indicated or even suggested in Kahn. Accordingly, the present claimed inventions are deemed novel and unobvious over the cited Kahn et al. EP reference.

(D) Applicants respectfully submit that claims 17-19 and 21-39 similarly define novel inventions over PCT International '909 to Kingham (PCT International WO 95/22909).

As stated in the Office Action, page 12, "Kingham does not teach the composition comprising the specific amounts of carbohydrate, protein and amino acids or peptide chain lengths as claimed."

Indeed, the Kingham reference appears focused on protein management for Parkinson's Disease for which the group of large neutral amino acids has relevance as they may cross the blood brain barrier. With this in mind, it is evident that the reference teaches formulating two groups of different amino acids. For ease of reference, in the published claim 1 the weight to weight ratio of the two groups of amino acids varies from about 3:1 to 6.5:1. The ratio is taught according to the reference can, however, only be obtained through the use of collagen. What should be noted is that no additional free leucine and/or phenolalyene is added according to the reference. This is in contrast to the present claimed invention which contemplates a composition having an additional free amount of leucine and or phenolalyene to obtain the insulin response needed to stimulate glycogen resynthesis following intense exercise. Therefore, the cited claims define over the reference.

(E) Dependent claims 35-37 are novel and unobvious. The references simply do not disclose or suggest these claimed inventions. The Examiner may wish to note former claims 1, 3, 10, 12 and 13 and also former claims 1, 3, 6, 10 and 12 in conjunction with these new claims.

As explained in the "Background of the invention" in the present specification (page 1), the applicants discovered that after exercise to exhaustion, a protein hydrolysate alone in a drink was not able to enhance the insulin response upon a carbohydrate load. This in

contrast after an overnight fast where a protein hydrolysate indeed can enhance the insulin response. See table 1, 1st study of the present application and PCT '641. Surprisingly, after exercise to exhaustion, no such response was found. An insulin response upon consumption of a carbohydrate drink could be elicited when phenylalanine and leucine were added to the composition. In fact, the insulin response was linear with the phenylalanine and leucine intake (table 1, 3rd study of the present application). This discovery was very surprising and unexpected.

In the composition of WO 97/39641 (Berthelson) no additional free leucine and/or phenylalanine is present. As explained in the present patent application the addition of free leucine and/or phenylalanine to the carbohydrate and peptide material containing composition as defined in the present patent application allows the insulin response required for stimulating the glycogen resynthesis after intense exercise.

Accordingly, Applicants submit that their claims define over the references, even if they were combined.

The application is considered in good and proper form for allowance, and the Examiner is respectfully requested to pass this application to issue.

It is also respectfully requested that absent allowance, the undersigned be contacted for purposes of scheduling a personal interview.

Respectfully submitted,

FITCH, EVEN, TABIN & FLANNERY

By: _____
Kendrew H. Colton
Registration No. 30,368

Fitch, Even, Tabin & Flannery
1801 K Street, N.W.

Suite 401L
Washington, D.C. 20006-1201
Telephone No. (202) 419-7000
Facsimile No. (202) 419-7007

APPENDIX

Amendments to the claims:

17. (Amended) A composition comprising (i) carbohydrate; (ii) peptide material; and; in addition, (iii) two free amino acids consisting of leucine and phenylalanine, wherein each [are] said amino acid is present in an amount in the range of 0.2 to 20 weight percent, calculated on dry matter basis.

19. (Amended) The composition according to claim 17 or 18, wherein said composition contains ~~an additional~~ another free amino acid which is selected from the group consisting of arginine and glutamine.

20. (Amended) The composition according to claim 19, wherein ~~each of~~ at least one of arginine and glutamine is present as an additional free amino acid~~, and each is present~~ in an amount in the range of 0.1 to 20 weight percent, calculated on dry matter basis.

35. (Amended) The composition according to claim 17, wherein said composition ~~comprises~~ has the form of an isotonic beverage or sports bar.